

EXHIBIT H

Autologous pubovaginal slings: back to the future or a lost art?

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Abstract: Stress urinary incontinence (SUI) is an under-diagnosed problem affecting up to 50% of women worldwide. SUI is a source of psychological distress to the individual and also imposes a financial burden to the individual and the health care system. The role of surgery in the treatment of SUI has evolved steadily in the last two decades. The synthetic mid-urethral sling and its different insertion methods have gained widespread popularity and are now the most frequently used surgical interventions for women with SUI in Europe. As the use of synthetic slings becomes more widespread, an increasing number of complications are being reported. With the recent concerns surrounding the use of synthetic transvaginal meshes in organ prolapse surgery, synthetic slings have been put under further scrutiny. It is imperative for health care providers to be aware of the current issues associated with synthetic slings and the alternative surgical options available. Traditional autologous pubovaginal slings (PVS) have re-emerged as a viable alternative to synthetic slings in light of the issues with synthetic slings. The re-adoption of autologous PVS has however, been slow due to the technical difficulty of the surgery and perceived higher morbidity rates. In this article, we will discuss the various aspects of autologous PVS and its indications as an alternative to synthetic slings. We will also touch on the current evidence and controversies for synthetic mesh slings.

Keywords: autologous pubovaginal sling, stress urinary incontinence, synthetic sling, erosions

Introduction

Stress urinary incontinence (SUI) is a common problem affecting up to 50% of women worldwide.¹ The autologous fascial pubovaginal sling (PVS) was popularized by McGuire and Lytton in 1978 who reported an 80% success rate in patients with intrinsic SUI. The synthetic mid-urethral sling (MUS), which was first introduced by Ulmsten in 1996, have largely replaced the traditional autologous PVS and are now the most frequently used surgical intervention in Europe for women with SUI.²

Following the recent concerns regarding the use of transvaginal mesh in organ prolapse surgery, synthetic MUSs have been put under scrutiny. Scotland's Regional Health Boards have received a request from the acting Medical Director for the National Health Service (NHS) Scotland regarding the suspension of the use of implantation of synthetic mesh slings in pelvic organ prolapse surgery pending further investigations.³ It is important for health care providers to be aware of the current concerns surrounding synthetic MUSs and the alternative surgical options that are available.

In this article, we will discuss the indications and results for autologous PVS sling placement and its viability as an alternative to synthetic slings. We will also review the current evidence and controversies surrounding synthetic mesh slings.

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Data extraction

We performed a systematic search on PubMed and on the Internet using the keywords “autologous slings”, “fascia slings”, “synthetic slings”, “mesh complications”, and “stress urinary incontinence”. Articles published in English between the years 1996 and 2015 were selected and vetted by both the authors. Animal and basic science studies were excluded from this review. Studies with multiple results published over a time period were all reviewed.

Preoperative assessment and indications for autologous slings

Preoperative evaluation is directed toward confirmation of the diagnosis of SUI and to exclude any concurrent urinary urgency symptoms. The presence of urinary urgency is recognized as the main cause of surgical failure in SUI surgery.¹ Preoperative evaluation for all patients includes a detailed urogynaecological history, physical examination, and urodynamic testing to confirm the presence of SUI. Additional pertinent points in the history include the presence of factors that will compromise the quality of the rectus fascia graft. Some of these factors include prior urethral or organ prolapse surgery and pelvic irradiation.¹ Specific urodynamic findings like the Valsalva leak point pressure and urethral pressure profile should be obtained, although this is not being performed uniformly.

Operative procedure for autologous pubovaginal sling

The first step of the surgery involves the harvesting of the rectus fascial graft. This is performed by making a Pfannenstiel incision 2 cm above the pubic symphysis with the dissection carried down to the rectus fascia. A 2 cm by 10–12 cm rectus fascia graft is marked out and the edges of the graft are dissected and freed from the underlying rectus muscle. Running sutures of ProleneTM 3-0 (Ethicon, Johnson & Johnson, Somerville, NJ, USA) are stitched onto each end of the graft with the sutures left long.

The second step of the surgery involves dissection of the wall of the vagina to create space for the placement of the autologous sling. An indwelling catheter inserted pre-operatively ensures that the bladder is emptied. A Sims speculum or a Lonestar retractor (CooperSurgical Inc., Trumbull, CT, USA) can be used to facilitate dissection and visualization. At least 50 mLs of local anesthesia (0.5% bupivacaine and 1:10,000 adrenaline) is injected into the vaginal epithelium for hydrodissection. In the author’s opinion, this is the single most important step as it aids in opening up the retropubic space and

prevents urethra or bladder injury during subsequent passage of the trocar. The bladder neck is identified by palpation of the catheter balloon. A vertical incision is made through the vaginal epithelium extending from 2 cm below the meatus to the level of the bladder neck. The dissection plane will be above the periurethral and pubocervical fascia.

The third step of the surgery is the creation of lateral vaginal flaps using a combination of sharp and blunt dissection. The flaps are then lifted up with Allis clamps and the ischiopubic ramus is palpated. Using the tip of the Metzenbaum scissors pointing upward, toward the ipsilateral shoulder, a window is created in the ipsilateral endopelvic fascia. The index finger is then placed over the urethra to push it medially and therefore, protecting the urethra during this step. The space between the endopelvic fascia and ischiopubic rami that has previously been hydrodissected out is then opened up by spreading out the scissor blades. It is crucial to stay underneath the ischiopubic rami to avoid injury to the urethra or bladder. The above steps are repeated for the contralateral side.

The fourth step involves placement of the graft. The ends of the graft sutures are tied to the blunt ends of the trocars and brought out through the vaginal incisions. By careful guidance behind the pubis, the trocars are brought out through the abdominal incisions. Ideally, a rigid cystoscopy with a 70-degree lens is then performed to check for any urethra or bladder injury before pulling out the trocars completely. The two free ends of the sutures are then pulled up while keeping an artery forceps in place between the fascia and periurethral tissue. The suture ends are then tied together above the rectus fascia with a finger placed underneath the knot to avoid excessive tension. This operation is then completed with closure of both vaginal and abdominal incisions.

Synthetic mesh slings

Synthetic MUS procedures have been proven to be an effective treatment for female SUI. The advantages of synthetic slings include a consistent sling material quality, predictable handling properties, and the assurance of sterility. As no autologous tissue is required, the usage of a synthetic sling also eliminates any harvest site related morbidities and patients undergoing the procedure have a shorter operative time and hospital stay compared to autologous sling patients.

The most commonly used synthetic sling material is polypropylene, a type I mesh material (Amid classification).¹ Polypropylene has loosely woven strands with pore sizes of 80 µm, permitting passage of macrophages to allow better host tissue ingrowth.¹ The comparison of the post-operative

histological changes show a greater amount of ingrowth of fibroblasts into both the sling material and normal tissue for synthetic slings as compared to autologous PVS.¹ The synthetic sling is a non-degradable material and hence, has the innate disadvantage of a higher incidence of sling erosion into the urethral or vaginal wall.

The common presenting symptoms of sling erosion include urgency, vaginal discharge, pain, or recurrent urinary tract infections. Most erosions are diagnosed at a median of 18 months after surgery.¹ Patient factors, such as a history of radiotherapy or urethral atrophy, play a role in sling erosions. Technical factors such as excessive sling tension, a dissection plane that is too close to the urethra, or occult perforation into the bladder or urethra during dissection are also believed to be some of the factors resulting in sling erosions.⁴ Apart from the patient and technical factors previously mentioned, the incidence of sling erosions is also dependent on the composition of the sling material. Synthetic slings are 15 times more likely to extrude into the urethra and 14 times more likely to erode into the vagina compared to autologous, allograft, and xenograft slings.⁴

Most studies agree that erosions resulting from synthetic MUSs require complete removal of all foreign material. The repair on the areas of erosion are then buttressed by soft tissue coverage such as a Martius flap. Erosion related complications will invariably lead to loss of urethral tissue or urethral length which often necessitates complex reconstruction surgery or secondary continence restoration procedures. Continence rates after successful urethral reconstructions are much lower than primary continence restoration procedures at 56%.⁴

Patients with sling erosion complications can present with recurrent extrusion or erosions, chronic pain, or recurrent abscesses. Anecdotally, Ugurlucan et al⁵ described a 36 year-old woman with trans-obturator sling-related vaginal erosion resulting in recurrent obturator abscesses with fistula formation 4 years after the initial insertion. The patient subsequently underwent drainage of the abscess with excision of the fistulous tract and removal of the necrotic material. Leanza et al⁶ also reported a late presentation of a woman 4 years after her initial surgery with tape erosion associated with myositis and abscesses of the obturator muscles. Both of these patients had presented with groin pain and difficulty walking. These cases emphasize the importance of long-term follow-up of these patients as sling erosion can present with late onset disabling complications. Magnetic resonance imaging is sensitive in detecting these late complications.

Widespread litigation involving synthetic mesh-related vaginal erosions have led to the US Food and Drug Administration (FDA) issuing a statement expressing concerns that the synthetic MUS procedure is at risk of long-term complications. Out of 2,874 reported cases of mesh complications in the FDA Manufacturer and User Device Experience database for the period from January 1 to December 31, 2008, 1,371 were associated with SUI repairs. This correlates with an average annual reporting rate of 2%.⁷ The FDA has since issued a Public Health Notification in 2008 to inform clinicians and patients of adverse events related to the urogynaecological use of surgical mesh and provided recommendations on how to mitigate mesh-related risks and counsel patients. The FDA is still currently looking into the literature regarding synthetic sling-related complications in the treatment of SUI and will issue a final report when the review is completed.⁸

Autologous PVS

The two most commonly utilized autologous slings are the rectus abdominis fascia or fascia lata graft slings. The rectus abdominis fascia sling is preferred by most surgeons due to a greater familiarity with the abdominal wall anatomy and the relative ease of harvesting. Both of these autologous slings have otherwise been shown to be equally effective.¹

The main advantage associated with autologous PVS is the negligible risk of erosion as they have minimal inflammatory and foreign body reaction. A study showed that the autologous graft remains viable with no signs of degeneration up to 4 years after the initial implantation.¹ This has been postulated as one of the reasons for the increased long-term risk of vaginal erosion with synthetic MUSs.¹

The disadvantages of autologous PVS include a longer operating time due to graft harvesting and repositioning of the patient. In addition, there are associated morbidities of the harvesting site such as bleeding and infection.

The success rates for autologous PVS in the treatment of SUI range from 46.9% to 90% with the longest follow-up period being 10 years⁹ (Table 1). These results have to be interpreted with caution due to the heterogeneity of the outcome measures and the short length of follow-up. Different outcome assessment tools are used and the Bristol Female Lower Urinary Tract Symptoms Questionnaire and the King's College Health Questionnaire are used in place of the standard International Consultation on Incontinence Modular Questionnaire. Khan et al⁹ reported their 10-year long-term results of a multicenter, randomized, controlled trial comparing tension-free vaginal tape, autologous PVS, and xenograft

Table 1 Summary of important papers on autologous PVS

| Study | Number of patients evaluated | Age (years) | Study objectives | Inclusion criteria |
|--|--|--|---|--|
| Khan et al ⁹ | Total: 162 TVT (63) AFS (61) Xenograft (38) | TVT: 61.2 (mean) AFS: 59.4 (mean) Xenograft: 62 (mean) | Multicenter, randomized, controlled trial comparing the long-term outcomes of TVT, AFS, and xenograft sling in the management of female SUI | Females (aged >18 years) with clinically and UDS confirmed SUI, requiring surgical intervention after failed trial of pelvic floor exercises |
| Morgan et al ¹⁰ | 247 | 54.5 (mean) | To report the long-term outcomes of PVS for the treatment of type II and type III SUI. To assess QoL impact | Women with type II or III SUI between 1993 and 1996 diagnosed with fluoroscopic UDS who received PVS |
| Athanasopoulos et al ¹¹ | 264 | 53 (mean) | To evaluate the efficacy of the autologous fascia rectus sling in treating female SUI | Women with SUI treated with autologous rectus fascia PVS between 2002 and 2005 by a single surgeon |
| Albo et al ¹² | Total: 520 PVS Group: 265 Burch group: 255 | Burch group: 52.2 (mean) PVS group: 51.6 (mean) | Multicenter, randomized, clinical trial comparing success rates between autologous PVS and Burch colposuspension | Women with stress predominant symptoms, a positive stress test and urethral hypermobility |
| Athanasopoulos and McGuire ¹³ | 32 | 46.4 (mean) | Retrospective single surgeon evaluation of the efficacy of the bulbourethral rectus autologous sling in treating male SUI | Men with SUI treated from 2001 to 2004 |
| Linder and Elliott ¹⁴ | 10 | 57 (median) | To evaluate a transobturator approach using AFS for the management of female SUI | All patients who underwent ATO MUS placement for female SUI |
| Chou et al ¹⁵ | 98 SUI: 46 MUI: 52 | 66 (median) | To assess the results of autologous PVS in women with MUI using a validated outcome score and identified risk factors for failure | Women who received a PVS for SUI/MUI confirmed by history, physical examination, and/or VUDS from 1995 to 2001 |

| Definition of outcome | Follow-up period | Results | Complication rates | Conclusion |
|--|---|--|---|---|
| Success: women reporting being completely "dry" or "improved" at follow-up Resolution of SUI: not mentioned. QoL impact: Urogenital Distress Inventory short form score <20: high rate of satisfaction Failure: more than one pad/day. Improved: one pad/day and only if this represented a reduction in pad use of >50% and reported as "satisfactory" by the patient. Cure: no leakage per urethra. Patient satisfaction: yes/no answer to the single, global assessment question: "Are you satisfied with the outcome of the performed operation?" Success: negative pad test. No urinary incontinence on 3-day bladder diary. Negative cough and Valsalva stress test. No self-reported symptoms. No retreatment for the condition Cure: no leakage per urethra or minimal leakage requiring only one pad/day. Improved: the use of two pads/day only if this represented a reduction in pad use $\geq 50\%$ and reported as satisfactory by the patient. Failure: leakage requiring more than two pads/day Success: patients reporting no leakage and no pad use | 10 years (median) 51 months (mean) 27.8 months (mean) 24 months 29.5 months (mean) 4 months (median) 3 years (median) | Success rates at 1-year vs 10-years: TVT: 93% vs 73% AFS: 90% vs 75.4% Xenograft: 61% vs 58% 10-year results not statistically significant Complete resolution of SUI with no urge incontinence: 88% High rate of satisfaction: 92% Cured and satisfied with outcome of operation: 85% Success rates were higher for PVS vs Burch procedure, for both the overall category of success (47% vs 38%, $P=0.01$) and the category specific to stress incontinence (66% vs 49%, $P<0.001$) Cured and satisfied: 46.9% No improvement: 53.1% Success: 80% | Reoperation for SUI rates: TVT: n=2 (3.2%) AFS: n=0 Xenograft: n=5 (13.1%) Sling failure: n=8 (3.2%) Other complications: 4% Overall: 29.16% | There is not enough evidence to suggest a difference in long-term success rates between AFS and TVT. However, there is some evidence that "dry" rates for AFS may be more durable than TVT. PVS are effective and durable, and significantly improve the QoL in patients with types II and III SUI. The free autologous rectus fascia sling is a highly effective technique for the treatment of female SUI with mild morbidity. Autologous fascial sling results in a higher rate of successful treatment of SUI but also greater morbidity than the Burch colposuspension. The free rectus fascia bulbourethral sling is a modestly effective technique for the treatment of male SUI with mild morbidity. The use of this method seems that it is suitable for selected cases. ATO urethral sling placement appears to be technically feasible with excellent short-term outcomes. Longer follow-up and larger series are needed for validation. Women with MUJ have a successful PVS outcome at a rate comparable to that in women with simple SUI. Increasing episodes of urgency and UI on the preoperative voiding diary correlated directly with surgical failure, while voiding frequently was associated with cure. |
| Cured: pad test <8 g loss and diary showing no SUI/UI episodes in 24 hours | | The cure/improved rate: SUI: 97% MUJ: 93% (not statistically significant) Increasing number of preoperative urgency and UI episodes correlated directly with PVS failure ($P<0.048$) | Post operative retention of urine requiring intermittent catheterization for 24 hours: n=1 Abdominal wall hematoma: n=1 Superficial wound infection: n=1 Perioperative cystostomy requiring transvaginal repair: n=1 MUJ group: troublesome UUI n=2, recurrent SUI n=1, prolonged retention requiring surgical revision n=1 SUI group: de novo UUI n=2 | |

(Continued)

Table 1 (Continued)

| Study | Number of patients evaluated | Age (years) | Study objectives | Inclusion criteria |
|----------------------------------|------------------------------|--|---|--|
| Welk and Herschorn ¹⁸ | 33 | 57 (median) | Retrospective single surgeon review of experience with autologous fascia PVS in the era of the MUS | Patients underwent autologous PVS between 2002 and 2009 and who have failed a median of two previous incontinence treatments |
| Milose et al ¹⁹ | 66 | 56.2 (mean) | To review the efficacy of autologous PVS after failed synthetic MUS | Women who underwent autologous PVS with rectus fascia after ≥ 1 failed synthetic MUS from 2007 to 2012 |
| Lee et al ²⁰ | 84 | 61 (mean) | Retrospective report on the long-term PVS outcomes between primary and secondary autologous fascia PVS | Women undergoing PVS between 1996 and 2011 |
| Rodrigues et al ²¹ | 232 | Fascial group: 47.3 years (median) Vaginal sling group: 48.5 years (median) | To compare the long-term results of SUI treatment involving fascial or vaginal sling operations | Women with confirmed SUI diagnosis urodynamically who underwent fascial or vaginal sling operations |
| Mitsui et al ²² | 29 | 64 (median) | To report the clinical and UDS outcomes of autologous rectus fascia for SUI. To determine UDS parameters that could predict the occurrence of postoperative voiding difficulty | Women with SUI treated with autologous rectus fascia PVS between 1998 and 2005 |

slings in women with SUI. They reported success rates or “dry” rates that favored the autologous PVS with none of the patients in the autologous PVS arm requiring further intervention for persistent SUI. They concluded that the autologous PVS may be more durable than the tension-free vaginal tape in the long-term.⁹ Morgan et al looked into their 4-year study

outcomes of 247 females with SUI who received autologous PVS, and reported an overall continence rate of 88%.¹⁰ They concluded that autologous PVS are effective, durable, and significantly improve the quality of life in patients with both type II and III SUI. Athanasopoulos et al also reported a success rate of 85% in 264 patients with autologous PVS.¹¹

| Definition of outcome | Follow-up period | Results | Complication rates | Conclusion |
|---|--|---|--|---|
| Success: one or no pad/day QoL impact: UDI-6 and IIQ-7. American Urological Association symptom Score | 16 months (median) | Median pad usage decreased to one pad/day ($P=0.003$). Overall QoL was mixed-to-delighted in 62% of patients | A third of the patients had postoperative urgency, and only one patient continued to use intermittent catheterization | The autologous fascia PVS has reasonable outcomes in a diverse population of patients, despite failure of other treatment modalities |
| Cure: patient, physician and The Michigan Incontinence Symptom Index reports of no stress or UI in the absence of requiring any additional incontinence procedures | 14.5 months (mean) | Cure: 69.7% Patients with pure SUI were significantly more likely to be cured of all incontinence (62.5%) than those women with MUI (30.0%) | Urinary retention >2 weeks: 12.1% Bladder perforation: 6.6% Deep vein thrombosis: 1.5% | Even after a failed synthetic mid urethral sling, autologous PVS is effective and cured SUI in 69.7% of cases |
| Success: UDI-6 question on SUI ≤ 1 , IIQ-7, QoL score measured by a visual analogue scale ≤ 3 , and no SUI re-treatment/operation | Primary: 73 months (median) Secondary: 82 months (median) | Surgical success rate: Primary: 76% Secondary: 52% Mean postoperative scores were not statistically significant for total UDI-6 score, IIQ-7, and QoL between groups | De-novo urgency and Frequency: 19% Early postoperative urinary retention resolved with catheter drainage: n=3 Intermittent catheterization at follow-up: n=2 | At long-term follow-up of average 7.4 years, primary and secondary PVS patients had comparable favorable functional outcomes with low morbidity. Secondary PVS patients had lower success rates with higher rate of additional procedures |
| Cured: no pads Greatly improved: rare dribbling episodes under extreme stress, but with no need for pads Improved: none to one pad/day Failure: continuing urine loss sufficient to disturb the whole day's activities. Worse: urine loss was intensified or new symptoms resulted from the surgery | Fascial group: 70.3 months (mean) Vaginal sling group: 44.9 months (mean) | Cured: Fascial group: 74.4% Vaginal sling group: 61.5% | Urinary retention: Fascial group 11.1% vs vaginal sling group: 8.6% Surgical complications were comparable between the groups | Sling operations are a safe and efficacious option to treat SUI. Shorter efficacy and fewer complications are observed in vaginal wall sling operations, while durable results, but with a higher rate of voiding dysfunctions compromising the long-term clinical satisfaction may be observed after excessive urethral suspensions, as in fascial sling suspension |
| Cured: no incontinence under any circumstances. Improved: $\geq 50\%$ reduction in incontinence. Failed: $< 50\%$ reduction in incontinence. Symptoms: pre- and postoperative urgency. UDS findings: including UFM, PVR, CMG, and PFS | At least 1 year | Cured: 23 patients (80%) Improved: three patients (10%) Failed: three patients (10%) | De-novo urgency: one patient Prolonged intermittent catheterization: eight patients | PVS with autologous rectus fascia is an effective treatment for SUI. Increase in post-operative urethral resistance, PVR > 100 mL and pre-operative Qmax ≤ 20 mL/s are risk factors for postoperative voiding difficulty |

Abbreviations: SUI, stress urinary incontinence; MUI, mixed urinary incontinence; PVS, pubovaginal sling; AFS, autologous fascial sling; ATO, autologous transobturator; TVT, transvaginal tape; MUS, mid-urethral sling; UDS, urodynamics; VUDS, video urodynamics; UFM, uroflowmetry; PVR, postvoid residual urine volume; CMG, filling cystometry; PFS, pressure flow study; UTI, urinary tract infection; UI, urge incontinence; IIQ-7, Incontinence Impact Questionnaire; UDI-6, Urogenital Distress Index; QoL, quality of life; UUI, urge urinary incontinence.

The complication rate was 29.2%, with postoperative urgency being the most common problem. They concluded that the autologous PVS is a highly effective technique for the treatment of female SUI with low morbidity rates.

The landmark trial by Albo et al¹² (the Stress Incontinence Surgical Treatment Efficacy [SISTER] Trial) comparing

autologous PVS to Burch colposuspension reported a higher success rates for autologous PVS compared to Burch colposuspension at 24 months (47% vs 38%, $P=0.01$). However, higher rates of complications such as urinary tract infections, voiding difficulty, and post-operative urge incontinence were reported in the autologous PVS group.¹²

Male SUI

With continual widening of the indications for autologous PVS in conjunction with development of novel methods of sling insertions, autologous PVS slings have been shown to be effective on selected cases of male SUI. Athanasopoulos and McGuire reviewed their results of the retropubic free rectus fascia bulbourethral sling in 32 men with SUI.¹³ Their definition of a cure was the absence of urinary incontinence or mild incontinence requiring only one pad per day. Forty-five percent of patients were cured and satisfied with the results with a mean follow-up 29.5 months. The advantages of rectus fascial slings are that they are cheap and easy to obtain with low risk of sling erosions. The authors conclude that the autologous PVS sling is a modestly effective and safe technique for the treatment of male SUI in selected cases.¹³

Transobturator insertion of autologous PVS

A small study of ten patients by Linder and Elliott reported on the results of transobturator insertion of fascial sling in females with SUI.¹⁴ Success was defined as the absence of urinary incontinence and no pad use. An 80% success rate was reported at a median follow-up of 4 months. The authors concluded that the transobturator approach is a feasible technique using a fascial sling with excellent short-term outcomes. However, a study with a larger cohort of patients and a longer period of follow-up is required to validate this approach.¹⁴

Mixed urinary incontinence

In addition to the treatment of simple SUI, the autologous PVS has also been reported to be effective in the management of mixed urinary incontinence (MUI). Chou et al reported their results on 131 women with MUI who underwent autologous PVS.¹⁵ The results showed that women with SUI and concurrent urge urinary incontinence have outcomes comparable to women with simple SUI at long-term follow-up of up to 7 years. Detrusor over activity was present in 26% of the women but was not a predictor of poor outcomes.¹⁵

Traditionally, autologous PVS is advocated for secondary or recurrent SUI surgery. Zimmern et al reported on the retreatment rates as part of the secondary analysis of the SISTER and the Trial of Mid-Urethral Slings trials.¹⁶ Six percent of women were re-treated within 5 years after failure of standard anti-incontinence procedures with either injection therapy or autologous PVS. Shah et al retrospectively reviewed 189 patients with sling erosions after synthetic

MUS insertion.¹⁷ They described a single step surgery with concomitant autologous PVS with total or near total removal of synthetic sling materials and urethral reconstruction. They concluded that this procedure can be safely performed in efforts to treat existing SUI or avoid future surgery for SUI. Our opinion is that any salvage surgery should be reserved until the patient has fully recovered from the initial synthetic sling removal. Welk and Herschorn¹⁸ and Milose et al¹⁹ both retrospectively reviewed women with recurrent SUI after a failed synthetic MUS or who had suffered from sling complications with autologous PVS chosen as a salvage procedure. Up to 69% of women experienced improvement in symptoms and they concluded that autologous PVS provides reasonable outcomes even after a failed synthetic MUS.^{18,19} Lee et al published their long-term results of autologous PVS with a median follow-up of 7.4 years and reported comparable functional outcomes in both primary and secondary PVS patients with low morbidity rates.²⁰

In addition to salvage surgery, PVS is also indicated in primary SUI with concomitant loss of urethra length due to trauma or in conjunction with simultaneous complex urethra reconstruction.¹ The durability of the autologous PVS also allows expansion of the indications to include treatment of primary uncomplicated SUI in young women who engage in vigorous exercises, obese individuals, or situations with potential poor tissue healing such as connective tissue disorders or uncontrolled diabetes mellitus. Autologous PVS can also be considered in patients requiring long-term intermittent catheterization as they have a much higher risk of urethral erosions if synthetic slings are used.

The risk of erosions associated with autologous PVS is rare, with only anecdotal case reports available. Handa and Stone reported the first case of autologous PVS sling erosion in the mid-urethra of a 34-year-old woman which was identified during urethroscopy performed after a 10-week history of urinary retention.²¹ Webster and Geridzen reported on a 73-year-old woman who developed urethral erosion after an autologous PVS following 2 weeks of intermittent catheterization.²² Golomb et al reported on a case of autologous PVS erosion into the mid-urethra in a 46-year-old woman that occurred after a traumatic episode of urethral catheterization.²³ These three cases were all treated with surgical excision of the graft without any serious complications.

The incidence of voiding dysfunction is reported to be higher in autologous PVS compared to synthetic slings, with rates ranging from 2% to 20.8%.^{24,25} Rodrigues et al reported on their long-term results in 232 women who underwent either

autologous PVS or synthetic MUS procedures for SUI, with a higher rate of voiding dysfunction observed in the fascial sling group.²⁶ Albo et al (SISTER Trial) also reported a higher incidence of voiding symptoms in the fascial PVS group compared to the Burch colposuspension group. In addition, they noted that all of the subsequent surgical procedures performed for bladder outlet obstruction were in the PVS group.¹² Risk factors for post-operative voiding dysfunction was studied by Mitsui et al.²⁷ They identified the risk factors for prolonged post-operative intermittent self-catheterization after PVS surgery and these included a post void residual volume of >100 mLs; Qmax ≤20 mL/s in preoperative urodynamic study. Nonetheless, the various studies on PVS surgery have not been able to show a consistent set of preoperative factors that can predict post-operative outcomes.²⁷

Conclusion

The autologous PVS is an effective and safe option for surgical treatment of primary and secondary SUI. It can be safely performed with a low morbidity rate and a negligible erosion risk in comparison to synthetic slings.

Moving forward, it is important for the clinician to obtain dedicated training in synthetic and/or autologous sling surgery. It is also the responsibility of the clinician to provide accurate pre-operative counseling to the patient and to ensure that the patient understands the procedure and the alternatives. It is very important that the risks associated with the synthetic sling treatment of SUIs and the possible long-term complications that may result in subsequent secondary procedures are made known to the patients.

Disclosure

The authors report no conflicts of interest in this work.

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